

Amendments to the Specification:

Please amend the paragraph at page 1, line 26 to page 2,
line 3 as follows:

FIG. ~~44~~ 41 depicts a tool for transoral treatment of GERD, disclosed in U.S. Pat. No. 5,887,594. This instrument a comprises a piercing device e having an elongated portion b, a manipulation section c and a hook portion d; and a securing device i having a connector f, a manipulation section g and a securing mechanism h. The piercing device e is inserted from the mouth to the stomach of a patient, and pulled up to the esophagus ~~[[k]]~~, with the hook portion d fixed at the upper stomach ~~[[j]]~~ thereby forming a fold of tissue (not shown). Then, the securing device i is inserted into the esophagus ~~[[k]]~~ of the patient, and the securing mechanism h fixes the fold consisting of the upper stomach ~~[[j]]~~ and the esophagus ~~[[k]]~~. When the fold is fixed, the intermediate portion is compressed to inward to form valve (not shown).

Please amend the paragraph at page 2, lines 4-17, as follows:

FIGS. ~~45~~ 42 to ~~49~~ 46 depict another transoral treatment method of GERD, disclosed in International Patent Publication No. WO99/22649. An instrument n has a rotatable fastener head p, which is rotatable at the distal end of a flexible tube o, and the rotatable fastener head p and portion of the flexible tube o that can touch the rotatable fastener head p have a male fastener q and a female fastener r, respectively. The flexible tube o has a rotatable grasper s at the distal end, and an opening ~~of~~ for an endoscope t to be inserted throughout the flexible tube o. First, the flexible tube o is inserted from the mouth to the stomach of the patient. The rotatable grasper s is drawn into contact with a junction v between the stomach and the esophagus. The rotatable grasper s is operated to hold the junction v. Next, the flexible tube o is advanced downward to suspend the junction v. The rotatable fastener head p is operated to penetrate the junction v with the male fastener q to engage with the female fastener r. Thus, the junction v and the middle part [[w]] are compressed to be protruded inward to form a protrusion x.

Please amend the paragraph at page 4, lines 19 and 20 as follows:

~~FIG. 10 depicts~~ FIGS. 10A and 10B depict a detail view of the distal end of a suture retaining device of the first embodiment.

Please amend the paragraph at page 7, lines 11-22 as follows:

~~FIG. 10 depicts~~ FIGS. 10A and 10B depict the suture retaining device 50 of the first embodiment. The suture retaining device 50 is slidably insertable in the lumen 9 of the guide 5, which is fixed on the outer periphery of the first endoscope 2. A distal section 51 has jaws, 52a and 52b, which may be forcep jaws with an opening and closing position. The jaws 52a and 52b each have a plurality of small protrusions 54a and 54b for preventing the suture 46 from slipping off the grasping surfaces 53a and 53b. The distal section 51 has, at the proximal end, a sheath 55 following the curve of the first endoscope 2 and a wire 56 capable of translating longitudinally in the sheath 55. The wire 56 has a slider handle ~~(not shown)~~ 57 at the proximal end, and the sheath 55 has a manipulation section ~~(not shown)~~ 58 at the proximal end. The slider handle and the manipulation section have, like the holding device 11, a serrated part (not shown) and serrations (not shown), which together act as a ratchet mechanism.

Please amend the paragraph at page 7, lines 23-26, as follows:

FIG. 11 depicts a knot pusher 61 comprising a distal end 62, a sheath 63 to be inserted in the channel 13 or 41 of the first endoscope 2 or second endoscope 6, and a knob ~~(not shown)~~ 64 for pressing the distal end 62 in the longitudinal direction. The distal end 62 has a slit 65 for engaging the suture 46.

Please amend the paragraph at page 8, lines 3-5 as follows:

The guide 5 is fixed on the outer periphery 4 of the first endoscope 2 at several points using a medical tape ~~(not shown)~~. The suture 46 is inserted in the lumen 8 of the needle tool 40.

Please amend the paragraph at page 9, lines 5-12 as follows:

FIGS. ~~15~~ 15A, 15B, 16A and ~~16~~ 16B depict penetrating the gastric and esophagus walls using the first embodiment. The second endoscope 6 is inserted parallel to the first endoscope 2. The distal end of the second endoscope 6 is positioned at a point 92 above the junction between the stomach and the esophagus while it is observed by the second endoscope 6. Then the second endoscope 6 is manipulated to bend the distal end 7 slightly toward the side of the greater curvature of the stomach. The sliding section 81 is moved distally against the body 80 to extend the sheath 42 out of the distal end 7 of the second endoscope 6, and to press an entering point ~~93~~ 93a.

Please amend the paragraph at page 9, lines 13-19 as follows:

The grip 45 is pressed forward to extend the needle 44 out of the sheath 42. Because the greater curvature ~~91~~ of the stomach at the cardia 90 has already been held by the holding device 11 and suspended with the first endoscope 2, the needle 44 pierces from the entering point ~~93~~ 93a through the mucous membrane 94, continuing at least through the proper muscularis 95 of the esophagus, then through the proper muscularis 96 of the stomach, and then through the mucous membrane 97 of the stomach, and exiting out of an exiting point ~~98~~ 98a of the cardia.

Please amend the paragraph at page 9, lines 20-25 as follows:

Next, the first endoscope 2 is inserted deeper in the body, and the tissue 91 is suspended lower, the needle 44 passes the entering point ~~93~~ 93b, the mucous membrane 94 of the esophagus, the proper muscularis 95 of the esophagus, the abdominal cavity 99, the serous membrane 100 of the stomach, the proper muscularis 96 of the stomach, the mucous membrane 97 of the stomach, and the exiting point ~~98~~ 98b at the cardia.

Please amend the paragraph at page 9, line 27 to page 10,
line 12 as follows:

FIGS. 17 ~~to 19~~ and 18 depict inserting and pulling the suture with the first embodiment. The suture retaining device 50 is inserted in the guide 5 and extended out in the stomach of the patient. The process is observed by the first endoscope 2. The suture 46 is pressed in the needle 44, and extended out in the stomach. With the suture retaining device 50 drawn into contact with the suture 46, the slider handle 57 is moved forward against the manipulation section 58 to open the jaws 52a and 52b. The suture 46 is held by the jaws 52a and 52b. The slider handle 57 is moved proximally against the manipulation section 58 to close the jaws 52a and 52b. The suture 46 is held by the small protrusions 54a and 54b on the grasping surfaces 53a and 53b of the jaws 52a and 52b. The jaws 52a and 52b are designed to minimize the chances that the suture 46 will slip off, ~~be damaged,~~ or be cut or damaged. When the serrated part ~~59~~ of the slider handle 57 is engaged with the serrations ~~60~~ of the manipulation section 58, distal movement of the slider

handle 57 will not be limited. Therefore, the jaws 52a and 52b hold and fix the suture 46 with hands-free operation of the slider handle 57 or the manipulation section 58. Next, the suture retaining device 50 is withdrawn from the guide 5 together with the suture 46. The serrated part 26 of the holding device 11 is lifted to disengage from the serrations 28. The slider handle 23 is moved forward to open the jaws 17a and 17b to release the tissue 91.

Please amend the paragraph at page 10, lines 13-18 as follows:

The steps illustrated in FIGS. ~~12 to~~ 17 and 18, and discussed above, are repeated to pass two sutures 46a and 46b through the following points: from outside the body, the channel 13 of the first endoscope 2, the patient tissue of the esophagus and the stomach, inside the guide 5, outside the body. The endoscopes 2 and 6 are withdrawn with the sutures 46a and 46b remaining in the body cavity. The resulting configuration is shown in FIG. 19.

Please amend the paragraph at page 10, lines 19-29 as follows:

FIGS. ~~20 and 19~~ to 22 depict formation of the artificial valve using the first embodiment. The suture 46a has ends 101a and 101b; the suture 46b has ends 102a and 102b. The ends 101a and 102a, which are on the side of the stomach, are tied to each other outside the ~~patient~~ patient's body. The free ends 101b and 102b, which are on the side of the esophagus, are pulled to draw the ends 101a and 102a into the body cavity. The ends 101a and 102b adjoin, and are fixed at exiting points 98a and 98b of the stomach. Then the ends 101b and 102b are pulled further to bring the gastric wall near the exiting points 98a and 98b close to entering points 93a and 93b in the esophagus. Thus, a junction 103 of the stomach and the esophagus between the exiting points 98a and 98b and the other entering points 93a and 93b is shortened to form an internal protrusion 104.

Please amend the paragraph at page 10, line 30 to page 11, line 10 as follows:

FIGS. ~~22~~ 23 to 27 depict fixing the sutures with the first embodiment. The ends 101b and 102b of the sutures 46a and 46b are tied outside the body to form a knot 105. The knot pusher ~~50~~ 61 is inserted in the channel 41 of the second endoscope 6, and its distal end ~~63~~ 62 is extended out of the distal end of the second endoscope 6. With the knot 105 engaged on the slit ~~68~~ 65, the second endoscope 6 and the knot pusher ~~50~~ 61 are inserted into the body cavity. Then, the ends 101b and 102b of the sutures are pulled to move the knot 105 and the second endoscope 6 into the body cavity. As seen in FIG. 25, when the knot 105 reaches the entering points 93a and 93b of the esophagus, the distal end ~~63~~ 62 is pressed against the entering points 93a and 93b while the ends 101b and ~~102~~ 102b are pulled to fix the knot 105. The above step is repeated several times to prevent the knot 105 from loosening. After the knot 105 is fixed firmly, the second endoscope 6 and the knot pusher ~~50~~ 61 are withdrawn out of the body cavity. The excess sutures 46a and

46b beyond the knot 105 are cut using endoscopic scissors (not shown), and are collected to finish the process.

Depending on the patient's symptoms, the above process will be repeated to form a plurality of stitches 106 to 109, as illustrated in FIG. 27, to form a larger protrusion ~~110~~.

Please amend the paragraph at page 11, lines 22-26 as follows:

Because both the second endoscope 6 and the needle tool 40 are provided separately from both the first endoscope 2 and the holding device 11, the operator independently controls suspension of the cardia and the ~~position~~ positions of the entering ~~point 93~~ points 93a and 93b to form valves of varying size according to the patient's particular symptoms.

Please amend the paragraph at page 12, lines 1-8 as follows:

In the second embodiment, a needle tool 110 is composed as follows. Two sheaths 111a and 111b are fixed at the distal ends 112a and 112b parallel to the distal end 113 of the second endoscope 6. The sheaths 111a and 111b are fixed at the proximal portion on the outer periphery of the second endoscope 6 using a medical tape at several points. The two sheaths 111a and 111b are fixed to the manipulation section 114 and accommodate needles 115a and 115b, which slide inside. Grips 116a and 116b are fixed to the proximal ends of the needles 115a and 115b and connected to connecting ~~sections~~ section 117 ~~and 117b~~ which ~~are~~ is detachable.

Please amend the paragraph at page 13, lines 26-28 as follows:

FIGS. 37 to ~~39~~ 40 depict the fifth embodiment of the present invention. The same components as the first embodiment are indicated by the same numbers, and their description will be omitted.

Please amend the paragraph at page 14, lines 8-14 as follows:

The endoscope 150 is inserted into the body of a patient until the distal end 153 enters the stomach. The endoscope 150 is manipulated to bend the distal bending section 159 to invert the distal end 153 so that it faces a direction substantially upwards. After the first optical system 151 observes the cardia 90, an actuator ~~155~~ opens grasping forceps 154 to touch the tissue 91. Then the actuator ~~155~~ closes the forceps 154 to fix the tissue 91. Next, the endoscope 150 is advanced deeper to suspend the cardia 90.

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Please amend the paragraph at page 14, lines 20-22 as follows:

The suture 46 is extended out of the needle 157, and held and fixed by the suture retaining device ~~162~~ 155 which extends out of the distal end 153 under observation of the first optical system 151.

Amendments to the Drawings:

FIGS. 1-46 have been replaced by the attached replacement sheets which more clearly show the features of the present invention.

FIG. 1 has been amended to add reference numeral 57 designating the slider handle in accordance with the disclosure in the specification at page 9, lines 31 and 32; and FIG. 1 has been amended to delete reference numeral 83, which is not described in the specification.

FIG. 5 has been amended to add reference numeral 29, in accordance with the disclosure in the specification at page 6, line 19.

FIG. 7 has been amended to remove a superfluous arrow and to remove reference numeral 83, which is not described in the specification.

FIG. 9 has been moved to a separate sheet from FIGS. 7 and 8.

FIG. 10 has been renamed FIG. 10A, and new FIG. 10B has been added corresponding to the magnified view in original FIG. 10; FIG. 10A has been amended to add reference numeral 51, in accordance with the disclosure in the specification at page 7, line 13; and FIG. 10B has been amended to add reference numeral 54b as shown in FIG. 10A.

FIGS. 12 and 13 have been amended to add reference numerals 3 and 11 as shown in FIG. 1.

FIG. 15 has been renamed FIG. 15A, and new FIG. 15B has been added corresponding to the magnified view in original FIG. 15; FIGS. 15A and 15B have been amended to change reference numeral 93 to 93a and to change reference numeral 98 to 98a to better accord with FIG. 22; and FIG. 15B has been amended to add reference numeral 44 as shown in FIG. 15A.

FIG. 16 has been renamed FIG. 16A, and new FIG. 16B has been added corresponding to the magnified view in original FIG. 16; FIGS. 16A and 16B have been amended to change reference numeral 93 to 93b and to change reference numeral 98 to 98b to better accord with FIG. 22; FIG. 16A has been amended to add reference numerals 2 and 6 as shown in FIG. 15A; and FIG. 16B has been amended to add reference numeral 44 as shown in FIG. 16A.

FIGS. 16A and 16B have been moved to a separate sheet from FIGS. 15A and 15B.

FIG. 17 has been amended to add reference numerals 2 and 44 as shown for example in FIGS. 15A and 16A.

FIG. 18 has been moved to a separate sheet from FIG. 17.

FIG. 23 has been amended to change reference numeral 63 to 62 and to change reference numeral 68 to 65, in accordance with FIG. 11.

FIGS. 24 and 25 have been amended to add reference numerals 6, 101b and 102b as shown in FIG. 23.

FIG. 28 has been amended to add reference numeral 114, in accordance with the disclosure in the specification at page 12, lines 5 and 6.

FIG. 29 has been amended to add reference numeral 110, in accordance with the disclosure in the specification at page 12, line 1.

FIG. 34 has been amended to add reference numerals 11, 140 and 143 as shown in FIGS. 32 and 33.

FIG. 35 has been amended to add reference numeral 141 as shown in FIG. 33.

FIG. 36 has been moved to a separate sheet from FIGS. 34 and 35.

FIG. 41 has been amended to add the label "Prior Art," as required by the Examiner.

And FIG. 46 has been amended to add reference character "o" as shown in FIG. 45.

Attachments: Replacement Sheets for Figs. 1-46
Annotated Sheets Showing Changes for Figs. 1, 5,
7-13, 15A and 15B, 16A and 16B, 17, 18, 22-25, 28-
30, 34-36, 41, 45 and 46